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10/612,298	07/02/2003	Byron E. Anderson	45240-105719	5133

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EXAMINER	
GROSS, CHRISTOPHER M	
ART UNIT	**PAPER NUMBER**
1639	

NOTIFICATION DATE	DELIVERY MODE
07/09/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-ch@btlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/612,298	ANDERSON, BYRON E.	
	Examiner	Art Unit	
	CHRISTOPHER M. GROSS	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,44 and 46-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,44 and 46-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/6/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responsive to communications entered 4/21/2008. Claims 5,44,46-51are pending. Applicant has added new claims 48-51. Claims 5,44,46-51 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) is acknowledged. This application claims benefit of provisional application(s): 60/394,176 filed 07/03/2002.

Withdrawn Objection(s) and/or Rejection(s)

The rejection of claims 5,44,46 under 35 U.S.C. 102(b) as being anticipated by Momany (EP 00180072) is hereby with drawn in view of applicant's amendments to the claims.

Miscellaneous Issues

The claim listing of 4/21/2008 includes claims 48-51 which are not compliant with 37 CFR 1.121 because of the following informalities: The claim status identifier is indicated a "currently amended" and the claims are marked up as if amended. Claims 48-51 should be indicated as "new" and should not be marked up. Applicant has provided a substitute claim listing on 6/27/2008 which corrects these issues.

Maintained Claim Rejection(s) - 35 USC § 103

Claims 5,44,46 and 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Momany** (EP 00180072) in view of **Barany et al** (US Patent 5235028).

The rejection of claim 48 is necessitated by Applicant's amendment to the claims.

Response to Arguments

Applicant argues: (i) not teach all elements are taught; (ii) the motivation to combine differs from applicant's.

(i) Applicant argues, see p 4 section II second paragraph (4/21/2008) the family of peptides (i.e. III) of Momany does not constitute a combinatorial peptide library, as urged by applicant as, bearing *all* the possible combinations of *all* the various amino acids defined to compose the elements of the library.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., *all* the possible combinations of *all* the various amino acids defined to compose the elements of the library) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues, see p 4 section II third and fourth paragraph (4/21/2008) the peptide family III of Momany only includes glycine for one of 11 options for J3 and claim 5 recites D-alanine, which is not included by Momany.

In this regard, reiterated from the last office action below, consistent with p 9-10 of the present specification, the aromatic tripeptides (i.e. Y3-Z3-E3) of Momany are taken as configured to enhance solubility by conjugation to *another* peptide (i.e. G3-J3) with G3 being Lysine which enhances solubility is acidic aqueous environments.

Furthermore, according to p 4 of Momany, J3 may be hydroxyproline, serine or threonine, which the examiner submits would further enhance solubility in polar solvents. On the other hand, the examiner submits, J3 being alanine, valine, leucine, isoleucine, leucine, cysteine, or methionine per Momany would enhance solubility in organic solvents.

In conclusion, the examiner respectfully submits peptide family III of Momany reads on the claimed subject matter as defined by the present specification on pp 9-10 and set forth in claims 5,44,46.

Applicant argues, see p 4 section II fifth paragraph (4/21/2008) the family of peptides (i.e. III) of Momany are not applicable to finding binding partners for *any* protein of interest.

In response to applicant's argument that the present invention is drawn to a library of peptides which may be applied toward finding binding partners for *any* protein of interest , a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant argues, see paragraph bridging pp 4-5 and p 5 third paragraph (4/21/2008) Momany in family III teaches a library of peptides wherein only 50 % contain 3 aromatic amino acids of D-Tyr, D-Trp and D-Phe, whereas claim 5 is drawn to 68 % (and claim 48 is drawn to 100%).

In this regard, the examiner submits in accordance with MPEP 2144.05 II A, Generally, differences in **concentration** or temperature **will not support the patentability of subject matter** encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Here, the claimed subject matter is drawn to a library comprising a plurality of D-peptides wherein at least 68% or 100% comprise three aromatic amino acids. The examiner agrees that Momany, in family III, teaches a library of peptides wherein 50 % contain 3 aromatic amino acids of D-Tyr, D-Trp and D-Phe. In this regard, the court has stated, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The examiner submits that the 50 % of Momany constitutes general conditions disclosed in the prior art. And as evidenced by the present specification on p 4 paragraph 0015, effective libraries may have 50%, 40%, 30% or as little as 25% enrichment in aromatic D amino acids. Thus, the examiner most respectfully submits the general conditions are taught by the prior art in the 50% enrichment of aromatic D amino acid per Momany, and that 68% or even 100%, set forth in claims 5 and 48 respectively, do not represent a critical value.

(ii) Applicant argues, see p 6 (4/21/2008) the polyethylene glycol, such as set forth in claim 47 is to enhance the water solubility of the peptide, rather than to provide better quality peptides, as advocated by Barany et al.

In response to applicant's argument that the polyethylene glycol enhances solubility, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Please note that the above rejection has been modified from the original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

New Claim Rejection(s) – 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5,44,46-49,51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection concerns new matter.

This rejection is necessitated by Applicant's amendment to the claims.

Claim 5 has been amended such that each D-peptide is from three to seven D-amino acid residues and wherein at least *68 %* of the D-peptides comprise at least three aromatic residues.

Applicant has successfully shown, see p 3 section I paragraph 3 (4/21/2008), implicit support in the disclosure for the pentapeptide library built by split synthesis in paragraph 0049 (p13) of the present specification for wherein at least *68 %* of the D-peptides comprise at least three aromatic residues, however applicant does not show 68 % with regard to three, four, six or seven residues.

The specification as originally filed provided no implicit or explicit support for at least *68 %* of the D-peptides comprise at least three aromatic residues when the D-peptides are three, four, six or seven residues. Similarly, applicant has not pointed to adequate support for the 100 %, 73 %, and 80 %, set forth in claims 48,49, and 51, respectively.

Claim 46 has been amended to recite D-Histidine as an aromatic amino acid. The specification as originally filed provided no implicit or explicit support combinatorial libraries wherein the aromatic D-amino acids are Histidine.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02

teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure*.

New Claim Rejection(s) – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5,44,46, 49, 50 and 47 rejected under 35 U.S.C. 103(a) as being unpatentable over **Dooley** (WO 94/26296 – IDS entry 5/6/2008) in view of **Barany et al** (US Patent 5235028).

This rejection is necessitated by applicant's amendments to the claims.

Dooley et al teach, throughout the document and especially the abstract, peptides which inhibit binding or the mu specific ligand to the opioid receptor, which were discovered using a competitive radio-receptor assay.

Dooley et al teach in claim 2, a hexapeptide family having the structure: Ac-D-Arg-D-Phe-D-Trp-D-Trp-Gly-Xaa-NH2 wherein Xaa is the D stereoisomer of the 20 common amino acids.

Said hexapeptide is synthesized from the C terminus to the N terminus, thus during solid-phase synthesis (see p 3 lines 6-8 of Dooley et al) thus, Dooley et al prepare H-D-Phe-D-Trp-D-Trp-Gly-Xaa-NH-resin as an intermediate. 100% of said peptide intermediate according to Dooley comprise three aromatic D-amino acids, meeting the "enrichment" limitation set forth in claims 5 and 49.

H-D-Phe-D-Trp-D-Trp-Gly-Xaa-NH-resin may be thought of as a tetrapeptide (H-D-Phe-D-Trp-D-Trp-Gly-), reading on claim 49 suitably constructed to enhance solubility through a Xaa. For example, consistent with paragraph 0037 (p 9) of the present specification, Xaa may be D-Lys or D-Arg, bearing a charge provides for better solubility in acidic aqueous solutions. H-D-Phe-D-Trp-D-Trp-Gly-D-Lys-NH-resin and H-D-Phe-

D-Trp-D-Trp-Gly-D-Arg-NH-resin plus the other peptide-resins of Dooley et al read on the library comprising...(i.e. open to additional elements) set forth in claims 5, 44,46 and 49.

Dooley et al do not teach a polyethylene glycol link to the support, such as set forth in claim 47.

Barany et al teach, throughout the document and especially figure 1A, resin (support) composed of beads for solid-phase peptide synthesis comprising polyethylene glycol (link) modified polystyrene (PEG-PS).

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to prepare the peptides of Dooley et al using the PEG-PS of Barany et al. PEG is equivalent to the equivalent to the polyoxyethylene to promote solubility per p 9, paragraph 0037 of the present speciation, thus said PEG is of Barany may be thought of providing a construct to enhance solubility. Therefore, H-D-Phe-D-Trp-D-Trp-Gly-Xaa-PEG-PS reads on the library comprising...(i.e. open to additional elements) , set forth in claim 50 by including H-D-Phe-D-Trp-D-Trp-Gly-Gly-PEG-PS and H-D-Phe-D-Trp-D-Trp-Gly-D-Ala-PEG-PS.

One of ordinary skill in the art would have been motivated to make the peptides of Dooley et al using the PEG-PS of Barany et al because PEG-PS provides better quality peptides, as indicated by Barany et al in example 10.

One of ordinary skill in the art would have had a reasonable expectation of success in applying the PEG-PS of Barany et al toward the synthesis of the peptides according to Dooley et al because both are concerned with preparing peptides (i.e. the

peptides of Dooley lie well with the scope of the disclosure of Barany et al, see figures 2-4).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
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cg

/Mark L. Shibuya, Ph.D./
Primary Examiner, Art Unit 1639